For Immediate Release

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ENZI COMMENDS HELP COMMITTEE APPROVAL OF LEGISLATION TO ALLOW FOLLOW-ON BIOLOGICS, PROTECT PATIENT SAFETY

Washington, D.C. – U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today commended the HELP Committee for approving legislation that will allow the Food and Drug Administration (FDA) to approve follow-on biologics in an expedited way, while preserving incentives to develop new therapies, without compromising patient safety.

"The 'Biologics Price Competition and Innovation Act of 2007' captures a delicate balance between access and innovation while maintaining the highest standard of safety," Enzi said. "Biologics are the skyscrapers of the drug world. They are towering monuments to medicine, science and biotechnology that can't easily be duplicated, and the slightest differences can be fatal. Our bill recognizes the need to make sure that biologic therapies are both safe and affordable."

"Biologics already are making it possible for thousands of Americans to live productive lives and changing the way we treat deadly diseases like cancer and infectious diseases. The legislation we've approved today holds new hope that we can further expand access of these remarkable medicines to more patients who need help combating deadly diseases. This bill is an important step to ensuring our aging population has access to innovative, reliable, and safe medicines."

"The Biologics Price Competition and Innovation Act" was introduced by Senator Ted Kennedy (D-MA), Chairman of the HELP Committee, Senator Enzi, Senator Orrin Hatch (R-UT), and Senator Hillary Clinton (D-NY).

"I would like to thank my colleagues for their hard work on this issue, particularly Senator Hatch, who has long been a leader in promoting affordable treatments and protecting patient safety," Enzi said. "The bill our committee approved today builds on the legacy of the Hatch-Waxman generic drug bill, and I believe it strikes the right balance to be just as successful as that landmark legislation."

Biologics Price Competition and Innovation Act of 2007

This Act amends Section 351 of the "Public Health Service Act" to provide for an approval pathway for safe biosimilar and interchangeable biological products (relying in part on the previous approval of a brand product) while preserving the incentives that have fueled the development of these life-saving medicines.

Approval Process — A biosimilar applicant is required to demonstrate that there are no clinically meaningful differences in safety, purity and potency between its product and the brand product. A demonstration of biosimilarity includes analytical data, animal testing and one or more clinical studies, unless such a requirement is determined by the FDA to be unnecessary.

FDA may approve a biosimilar product as interchangeable, meaning it can be substituted for the brand product without the intervention of the health care provider who prescribed it. Showing interchangeability requires evidence that the biosimilar product will produce the same clinical result as the brand product in any given patient and that it presents no additional risk in terms of safety or diminished efficacy if a patient alternates or is switched between products.

The legislation allows, but does not require, the FDA to issue guidance documents to inform the public of the standards and criteria the agency will use in approving biosimilar and interchangeable products. Development of these guidance documents will require public input. Applications can be filed in the absence of guidance documents.

Exclusivities — The Act provides incentives for the development of both new life-saving biological products and interchangeable biosimilar products: 12 years of data exclusivity for the brand company during which a biosimilar product may not be approved, and 1 year of exclusivity for the first interchangeable biological product.

Patent Resolution — The legislation includes a multi-step process to identify and resolve patents that the biosimilar product may infringe. The biosimilar applicant must provide its application and information about its manufacturing process to the brand company. A series of informational exchanges then occur in which the biosimilar applicant and the brand company identify patents in question and explain their views as to their validity or infringement.

The two parties then either agree to a list of these patents to be litigated first or exchange lists when they can't, and the brand company must then sue the biosimilar applicant within 30 days to defend them. If the brand company wins a final court decision that a patent is valid and infringed by the biosimilar product before the 12-year data exclusivity has run, the court must enjoin infringement of the patent until it expires. For identified patents not included in this initial litigation, the biosimilar applicant must give the brand company notice 180 days before it intends to launch its product, and the brand company may then seek a preliminary injunction to block the launch.

If the brand company fails to identify a patent, it can't later enforce it against the biosimilar product. If it fails to defend a patent identified for initial litigation, the brand company may

only later receive a reasonable royalty. If the biosimilar applicant fails at any step to do what it is required to do, the brand company may immediately defend its patents.

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